

## **REMARKS**

### **Status of the Claims**

Claims 21-36 are currently pending in the application. Claims 1-7, 9, 10 and 16-20 have been cancelled without prejudice or disclaimer. Claims 1-7, 9, 10 and 16-20 stand rejected. New claims 21-36 have been added. No new matter has been added by way of the present amendments. Specifically, new claims 21-36 are supported by the as-filed claims. Reconsideration is respectfully requested.

### **Interview**

Applicants and Applicants' representatives thank the Examiner and the Supervisory Patent Examiner for granting an interview which was conducted on March 2, 2006. The substance of the interview is summarized in the Interview Summary sheet of record. In brief, it was agreed that the separation of the claims into claims directed to determining a prognosis and claims directed to providing treatment guidance would be acceptable and would not trigger a restriction requirement. Further proposed amendments to claims 1, 3 and 6 as presented in the new claims herein were discussed.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-7, 9, 10 and 16-20 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (*See*, Office Action of November 14, 2005, at page 3). Claims 1-7, 9, 10 and 16-

20 have been cancelled without prejudice or disclaimer, thus obviating the rejection as to these claims.

The Examiner states that it is not clear “how the purpose stated in the preamble of the claims is related to the active steps of the claims” because it was believed that the term prognostication somehow implied determining whether the subject has developed a neoplasia. (*Id.*). However, the term prognostication, as was recited in claim 1, means determining the progression of a neoplasia already known to exist, not whether or not a neoplasia is present.

To further clarify this point, new claim 21 recites, in part, a “method for guiding the application of an adjuvant therapy in treating a human patient having a neoplasia.” Additionally, new claim 22 recites, in part, a “method for determining a prognosis of a human patient having a neoplasia.” Thus, the word “prognosticating” is no longer recited by the presently pending claims.

### **Rejections Under 35 U.S.C. § 112, First Paragraph**

#### **Enablement**

Claims 1-7, 9, 10 and 16-20 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*Id.*). Claims 1-7, 9, 10 and 16-20 have been cancelled without prejudice or disclaimer, thus obviating the enablement rejection as to these claims.

The Examiner states that while the specification is “enabling for p53 mutational analysis and node status analysis, [it] does not reasonably provide enablement for providing guidance for the treatment.” (*Id.*). The Examiner appears to indicate that the specification does not support

providing treatment guidance. (*Id.* at page 4). However, new claim 21 recites, in part, a “method for guiding the application of an adjuvant therapy in treating a human patient having a neoplasia.” Additionally, new claim 22 recites, in part, a “method for determining a prognosis of a human patient having a neoplasia.” Thus, the claims directed at guiding treatment in a subject based on node status and p53 mutational analysis are directed at determining whether or not adjuvant therapy would be advised. For instance, new claim 21 recites, in part, “applying the adjuvant therapy to the patient if the survival rate according to part c) following the adjuvant therapy is significantly improved.”

Thus, the present claims are not directed to “what kinds of treatment is good for each of those patients in the different subgroups classified based on nodal status and the p53 mutational status,” but instead are directed at a simpler, more basic question of whether or not adjuvant therapy should be considered at all. The specification fully enables the presently pending claims for these reasons and reasons discussed at the interview.

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Amendment dated April 14, 2006  
Reply to Office Action of November 14, 2006

Docket No.: 2962-0120P

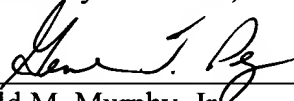
**CONCLUSION**

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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